

(19)



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11)

EP 1 252 863 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:

30.10.2002 Bulletin 2002/44

(51) Int Cl.7: A61B 10/00

(21) Application number: 02102018.5

(22) Date of filing: 20.09.1994

(84) Designated Contracting States:
DE FR GB

(30) Priority: 20.09.1993 US 124272
30.09.1993 US 129653
29.10.1993 US 146447

(62) Document number(s) of the earlier application(s) in
accordance with Art. 76 EPC:
94929247.8 / 0 720 442

(71) Applicant: BOSTON SCIENTIFIC CORPORATION
Watertown, MA 02172 (US)

(72) Inventors:

• Robinson, Donald
MA 01748, Hopkinton (US)

• Banik, Michael S.
OH 45241, Cincinnati (US)

(74) Representative: Brunner, Michael John et al
GILL JENNINGS & EVERY,
Broadgate House,
7 Eldon Street
London EC2M 7LH (GB)

Remarks:

This application was filed on 09 - 07 - 2002 as a
divisional application to the application mentioned
under INID code 62.

(54) Multiple biopsy sampling coring device

(57) This invention is a device for collecting a sam-
ple tissue comprising a device body having a forward

facing tissue opening, a severing element to sever tis-
sue within the opening, and a storage space to store
multiple tissue samples.

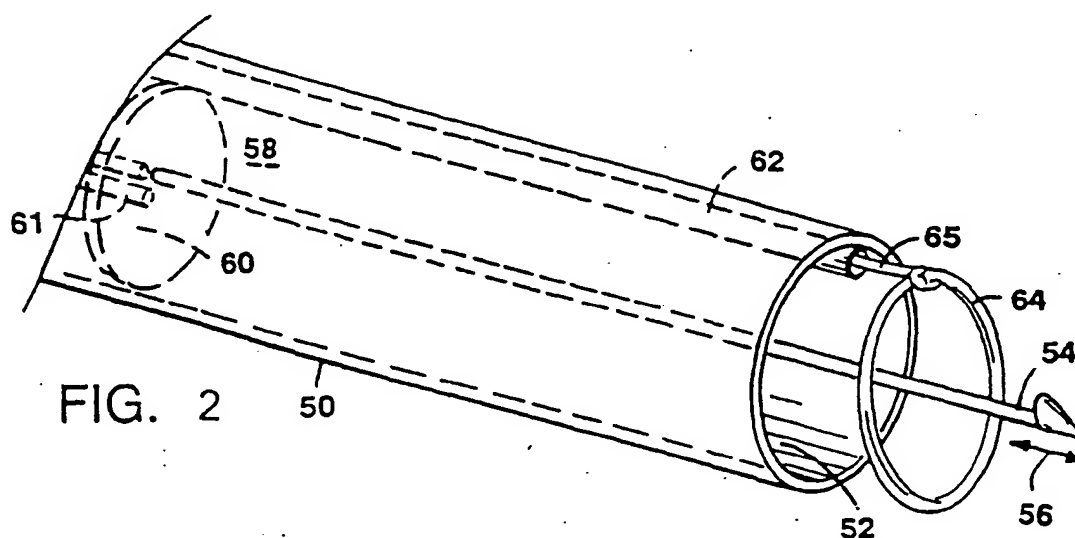


FIG. 2

EP 1 252 863 A1

Description

[0001] This invention relates to taking samples of tissue from the body for biopsy analysis.

[0002] Tissue samples can be examined in a laboratory to determine the presence of a pathological disorder (e.g. malignancy). Often, the samples must be obtained from deep within the body using a medical sampling instrument. It is usually best to obtain several samples around the location where the disorder is suspected so that the presence and progress of disease, if any, can be accurately determined. The samples must be catalogued according to the location from which each sample is taken and the integrity of the samples must be maintained for the subsequent laboratory analysis.

[0003] US 4,785,826 discloses an instrument used to gather tissue. The device retains a gathered tissue specimen by closing the end of a hollow member while the member is in the gathering position.

[0004] According to the present invention there is provided a device for collecting from a tissue surface, a sample of tissue, including tissue specimens, polyps, or the like, comprising:

a device body defining a forward-facing tissue receiving opening of substantially predetermined width through which tissue may pass when said opening is near said tissue surface,
a severing element actuatable across the width of said tissue receiving opening when tissue from said surface extends through said opening for severing said tissue from said surface, and
a storage space proximal of and adjacent said opening for storage of multiple successively taken samples by repeatedly passing tissue through said opening and actuating said severing element, characterised in that

said severing element comprises a cutting loop, said cutting loop being actuatable between an open configuration that is oriented generally coaxially with said tissue-receiving opening and a closed configuration in which the loop passes across said opening to sever said tissue.

[0005] The cutting loop may be actuated by a control wire extending parallel with the axis of said body.

[0006] The control wire may pass through a lumen extending to an opening adjacent said tissue-receiving opening.

[0007] The cutting loop may be actuated by withdrawing it into said lumen.

[0008] The device may further comprise a retractor extendable distally beyond said opening and said cutting loop for engaging said tissue surface and retractable proximally to draw tissue through said tissue-receiving opening and cutting loop.

[0009] The retractor may be a spear-form element adapted to pierce tissue and having a retaining barb on

its distal end.

[0010] Preferably, a cutting guide is also provided on the outer surface of the body of the device proximal of said tissue-receiving opening, said guide formed by a slot including a cutting edge with a portion communicating with the periphery of said opening such that tissue prolapses into said slot when the periphery of said device is placed against said tissue surface, said device being rotatable about its axis so that tissue in said slot is cut by said cutting edge and tissue passes through said tissue-receiving opening, the depth of said cut and the width of tissue passing through said opening being determined by the degree of rotation of said body and the width of said guide.

[0011] Preferably, the depth of said cut is 1-2 mm for each rotation of said device.

[0012] The invention has many advantages. For example, sampling into tissue to a desired depth can be achieved by controlling the amount of sample that enters the forward-facing coring opening of the device, by, for example, controlling how deeply the device is advanced into a tissue wall or how much tissue is drawn through the opening using a retractor. Thick samples can be taken in a single sampling action; for example, samples beyond the mucosal layer (submucosal sampling) can be taken from a site in a single sampling action. Careful control of sampling depth also permits samples to be taken from very thin tissue walls without puncturing the walls. Multiple samples can be taken, stored in the device, and maintained in a hydrated state without removing the device from the body.

[0013] An example of the present invention will now be described with reference to the drawings, in which:

Fig. 1 is a perspective view of an embodiment of the invention being delivered into the body through an endoscope;

Figs. 2-2e illustrate the structure and use of an embodiment of the invention;

Figs. 3-3e illustrate the structure and use of another embodiment of the invention;

Fig. 4 illustrates the structure and use of another embodiment of the invention;

Figs. 5-5c illustrate the structure and use of another embodiment of the invention.

[0014] Referring to Fig. 1, the device 10 for multiple biopsy sampling may be delivered into the body through the channel of an endoscope device 11 (e.g., gastroscope, sigmoidoscope, or colonoscope). The endoscope device typically has a length of about 100-250 cm and a channel diameter of 2.0 - 3.8 mm, typically about 2.8 mm. A distal sampling portion 16 is extended from the endoscope for cutting and storing a sample of tissue from a body surface 18 of a patient (e.g. from a surface in the gastrointestinal tract or bronchial tract). The device has a diameter of preferably around 1.8 - 2.4 mm, typically about 2.3 mm or less and is of sufficient flexi-

bility so it passes easily through the channel when the endoscope follows a tortuous body passageway. The endoscope includes other lumens for water, air, suction, and viewing. Devices according to the invention can be adapted to be introduced to sites (e.g., urinary tract, reproductive organs, cardiac tissue, or the like) deep within the body by other means. For example, a device can be configured with a lumen so that it can be advanced over a guidewire, e.g., in vascular applications. The device may be passed through an introducer or guiding catheter in, e.g., cardiac applications. The sampling and storage arrangements may be useful in open surgery applications, in breast biopsy in which the device is pressed directly into tissue, laproscopic biopsy in which the cutting element is positioned through a tubular instrument extending through the skin, and percutaneous needle biopsy in which the device is directed through a hole in the skin to sample an internal organ, e.g., the liver.

[0015] Various cutting element arrangements are possible; for example, elements that rotate about a pivot point and are biased by a spring could be provided. Arrangements with more than two cutting elements may also be used. One of either the cutting member or tubular member may be moveable and the other stationary. The components that experience sliding motion may include a lubricant. For example, the interior wall of the inner tubular member may include a low friction coating 17, e.g., of teflon, silicone, or a hydrogel, so that samples within the tube and storage space slide easily. The outer surface of the inner tubular member and/or the inner surface of the outer tubular member may also include a lubricant to ease sliding motion. (Other sliding components in other embodiments, shown below, e.g., control wires and cutting loops may also include a lubricant.)

[0016] Referring to Figs. 2-2e, in this embodiment, a tubular member 50 defines at its distal end, a forward-facing distal opening 52 and includes within a retractor 54, preferably a spear-form element with a barb as shown, or another retractor type as discussed above. The retractor 54 is axially movable (arrow 56) and extends through a storage space 58 bounded on the proximal end by a sample stop 60. The axial motion of the retractor 54 and stop 60 are controlled separately; the retractor passes through an aperture in the stop and the stop is controlled by a separate member 61. (Alternatively, in other embodiments, the retractor may be attached to the stop so they move axially together.)

[0017] The embodiment also includes a wire-form cutting loop 64. The loop, shown extended in Fig. 2, is oriented with its centre roughly along the axis of the device and sized to approximate or be larger than the outer diameter of the distal portion of tubular member 50. The loop 64 may be formed of a shape memory metal, e.g., nitinol or other elastic materials, such as cold-worked stainless steel, or a plastic, that can be preformed and trained so it is capable of being repeatedly withdrawn

into a lumen 62, where the loop is in a compacted state, and then extended therefrom to open and orient the loop as shown.

[0018] A control wire 65, for retracting and extending the loop, may be made integrally or attached to the loop. The lumen 62 may be constructed integrally with the tubular member 50.

[0019] Referring particularly to Fig. 2a (cross-sectional view), in use, the control wire 65 is extended distally so the cutting loop 64 is formed and positioned just distal of the open end 52 of the device 50, which is brought in proximity of the surface 18 where a sample is to be taken. The retractor 54 is extended distally (arrow 66) so it pierces the tissue surface 18. As the retractor 54 is extended distally, previously taken samples, samples 1-4, are displaced proximally.

[0020] Referring particularly to Fig. 2b, the retractor 54 is then withdrawn proximally (arrow 68), bringing tissue into the distal end opening of the member 50 and through the cutting loop 64.

[0021] Referring particularly to Figs. 2c, 2d (end on view, tissue not shown) and 2e, the tissue sample is severed from the surface 18 by withdrawing the control wire 65 proximally, which draws the loop 64 through tissue across the end opening 52 of the member 50. With the loop 64 substantially withdrawn in the lumen 62, the new sample, sample 5, is completely severed from the surface 18 (Fig. 2e). The process can be repeated by extending control wire 65, distally and hence forming the cutting loop 64, to cut the next sample, as shown in Fig. 2a.

[0022] Referring to Figs. 3-3e, another embodiment is shown. In this case, the device includes near the end opening 54, a cutting guide 70, formed in the wall of the tubular body adjacent the distal end. (The guide does not extend across the diameter of the end opening; rather, it is formed by cutting out a portion of the side wall of a tube.) The device further includes a cutting loop 72, having an open diameter larger than the diameter of the end 54 of the device.

[0023] In this embodiment, the depth of the sample cut can be carefully and conveniently controlled. The end 54 of the device is pressed against the tissue wall. (The end need not be sharpened to a tissue-cutting edge.) Tissue prolapses into the gap 76 proximal of the cutting guide 70. The gap is bordered by sharpened cutting edges 78, 78*. Thus, tissue cutting occurs only during rotation of the device. The depth of tissue cut during rotation is controlled by the width of the cutting guide W from the end 54 of the device to the lowermost proximal portion of the cutting edge 78. Thus, for a single rotation, a helical, circumferential cut through tissue is made to a depth no greater than the width W. The cutting loop 72, of an enlarged diameter, slides distally over the body of the device as the distal end enters the tissue. The loop 72 can be retracted to sever the sample of controlled depth from the body surface. An axially movable retracting arm 74, passing through a slotted lumen 76,

may also be provided to pull samples into the body of the device for storage. The lumen slot 77 allows the radially extending arm to be withdrawn proximally. An optional stop member 80, in this case a conical member that widens to greater diameter in the distal direction, can be positioned on the device to assure that coring beyond a predetermined depth does not occur. The stop member can be an umbrella-type assembly that changes the axial location of the end of the stop by opening and closing radially, as shown. Other stop mechanisms, such as an inflatable balloon or a spring-form wire may also be used. Apertures 82 are placed in the body of the device so that fluids (e.g. ambient body fluids) can easily pass to contact previously taken samples while they are being stored to keep them from drying out, which can damage cell structure and make pathological examination more difficult. Saline solution or the like may also be passed from proximal portions e.g. through the main lumen, into contact with samples. The saline may flow out of the apertures 82.

[0024] The body of the device is preferably formed of a highly torqueable plastic tube, but for the distal end including the cutting tang 70, which is preferably formed of metal. The proximal portions of the device include a wire coil body 83 that can be passed through torturous passageways, e.g., an endoscope channel. The shape of the guide can be varied to affect various depths and cutting profile. Typically, the most distal end of the guide terminates in a sharp point, as shown, to help start the cutting when rotation begins. The control wire and/or the cutting loop may be made of braided wires. The cutting loop may be shaped along its inner edge to form a sharp cutting surface. The cutting loop may also be heated e.g., by electric current. The end of the tubular member may flare outward, distally to facilitate drawing tissue into the end.

[0025] Referring particularly to Fig. 3a, in use, the enlarged cutting loop 72 is extended and the distal end of the device, including front-facing surface of the cutting guide 70, is pressed against the surface 18 of tissue from which a sample is to be taken. Tissue prolapses into the gap 76 of the cutting guide. (This embodiment does not include retractor 74 or stop 80. The mechanical simplicity of this embodiment is an advantage, since, it can be delivered through tighter lumen tracts to hard-to-reach sampling sites.)

[0026] Referring particularly to Fig. 3b, the body of the device is pressed against the tissue and rotated about its axis (arrow 88), causing tissue in the gap 76 to be cut by the sharpened edges 78, 78*.

[0027] Referring particularly to Fig. 3c, as the distal end of the device enters the tissue due to the rotating cutting motion, the cutting loop 72 is pushed proximally, over the outside of the body.

[0028] Referring particularly to Fig. 3d, when the device has entered the tissue to a desired depth, for example, a single rotation of the device cutting to a depth equal to the width of the guide, a sample can be severed

from the tissue surface 18 by withdrawing the cutting loop 72 into the lumen 52. The cutting loop, drawn back into the lumen 62 over the body, cuts the tissue across the opening of the distal end of the device.

5 [0029] Referring particularly to Fig. 3e, with the cutting loop 72 drawn substantially completely into the lumen 52, a thickness-controlled sample is severed from the tissue surface 18. The procedure above can be repeated to take an additional sample if desired.

10 [0030] Referring to Fig. 4, another embodiment is shown. In this case, the device includes a tubular member 100, having an open tubular distal end 102. The distal end 102 is sharpened so the device may be urged into tissue to a desired depth, by extending the device distally axially. A cutting wire 104 is provided across the circumference of the device. To sever a tissue sample, the body of the device is rotated about its axis (arrow 106). For each sample taken, the device produces two sample halves. For example, sample halves 110, 112 of sample 108, since the tissue has been bisected by the cutting wire 104 when the device was urged distally into the tissue surface. The device may further be provided with retractor members 114, 116, which may be in the form of a spear-form element or other retractors as described above.

25 [0031] Referring to Figs. 5-5c, another embodiment for severing tissue is shown. In this case, an arrangement for severing tissue across the distal end 130 of a tube 132 includes a pair of wire cutting elements 134, 136, that join at respective ends to control wires 138, 139, that are axially moveable in lumens 140, 141. In the configuration shown in Figs. 5 and 5a (end-on view), the control wires are extended, which bows the wire cutting elements 134, 136 outward, causing them to conform to the outer end of the tubular member so that tissue can extend beyond the wires and enter the distal end of the tube. In the configuration of Figs. 5b and 5c, the control wires are drawn proximally, causing the cutting elements 134, 136 to close across the end opening of the tube, cutting tissue so that a sample can be severed from a tissue surface. In other embodiments, a single control wire is used; the other ends of the cutting elements are attached to the end of the tube.

40 [0032] The features discussed above with respect to the various embodiments, e.g. arrangements for receiving tissue through the opening of the devices and arrangements for severing tissue from a surface, can be combined in further embodiments.

50 Claims

1. A device (10) for collecting from a tissue surface (18), a sample of tissue (1-5), including tissue specimens, polyps, or the like, comprising:

55 a device body (20) defining a forward-facing tissue receiving opening (19) of substantially pre-

determined width through which tissue (1-5) may pass when said opening (19) is near said tissue surface (18),

a severing element (64) actuatable across the width of said tissue receiving opening (19) when tissue (1-5) from said surface (18) extends through said opening (19) for severing said tissue (1-5) from said surface (18), and a storage space (25) proximal of and adjacent said opening (19) for storage of multiple successively taken samples (1-5) by repeatedly passing tissue (1-5) through said opening (19) and actuating said severing element (64), **characterised in that**

said severing element (64) comprises a cutting loop (64), said cutting loop (64) being actuatable between an open configuration that is oriented generally coaxially with said tissue-receiving opening and a closed configuration in which the loop passes across said opening (19) to sever said tissue (1-5).

opening (19), the depth of said cut and the width of tissue passing through said opening being determined by the degree of rotation of said body and the width of said guide.

8. The device (10) of claim 7, wherein the depth of said cut is 1-2 mm for each rotation of said device (10).

2. The device (10) of claim 1, wherein said cutting loop (64) is actuated by a control wire (65) extending parallel with the axis of said body (20).
3. The device (10) of claim 2, wherein said control wire (65) passes through a lumen (62) extending to an opening adjacent said tissue-receiving opening (19).
4. The device (10) of any of claims 1 to 3, wherein said cutting loop (64) is actuated by withdrawing it into said lumen (62).
5. The device (10) of any of claims 1 to 4, further comprising a retractor (54) extendable distally beyond said opening (19) and said cutting loop (64) for engaging said tissue surface (18) and retractable proximally to draw tissue (1-5) through said tissue-receiving opening and cutting loop (64).
6. The device (10) of claim 5, wherein said retractor (54) is a spear-form element adapted to pierce tissue and having a retaining barb on its distal end.
7. The device (10) of any of claims 1 to 6, further including a cutting guide (70) on the outer surface of the body (20) of the device proximal of said tissue-receiving opening (19), said guide (70) formed by a slot including a cutting edge with a portion communicating with the periphery of said opening such that tissue prolapses into said slot when the periphery of said device (10) is placed against said tissue surface, said device (10) being rotatable about its axis so that tissue in said slot is cut by said cutting edge and tissue passes through said tissue-receiving

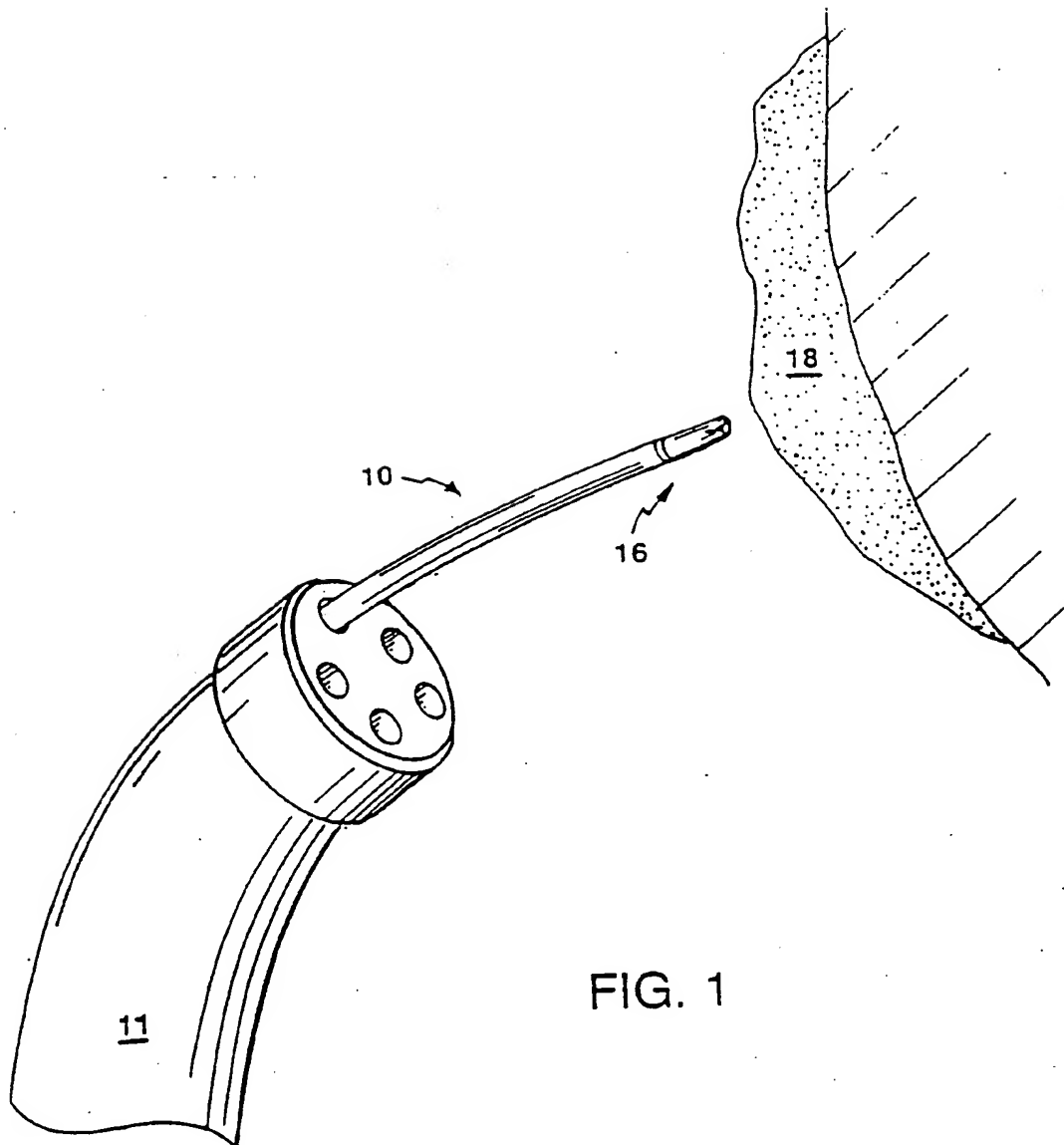
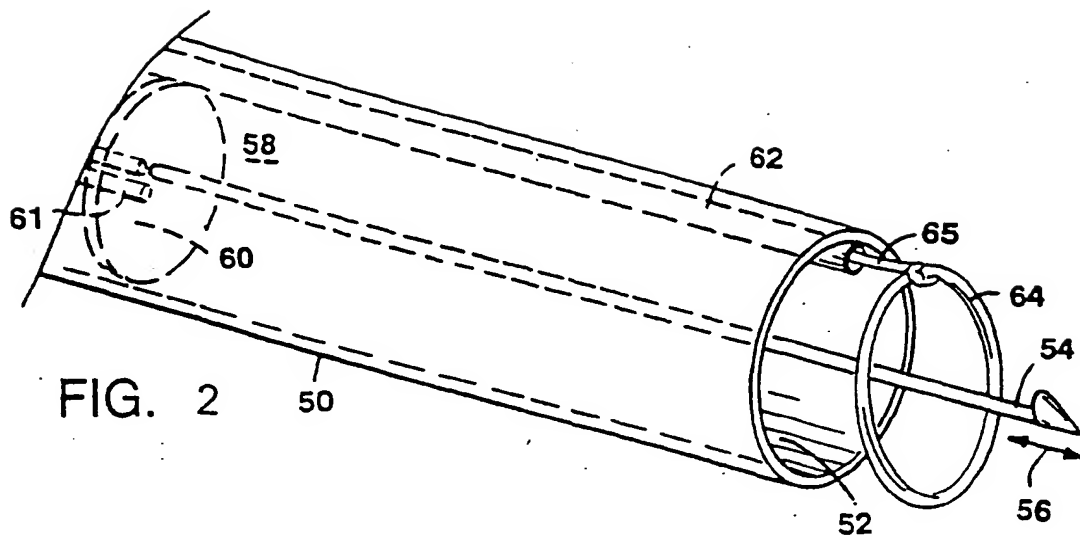


FIG. 1



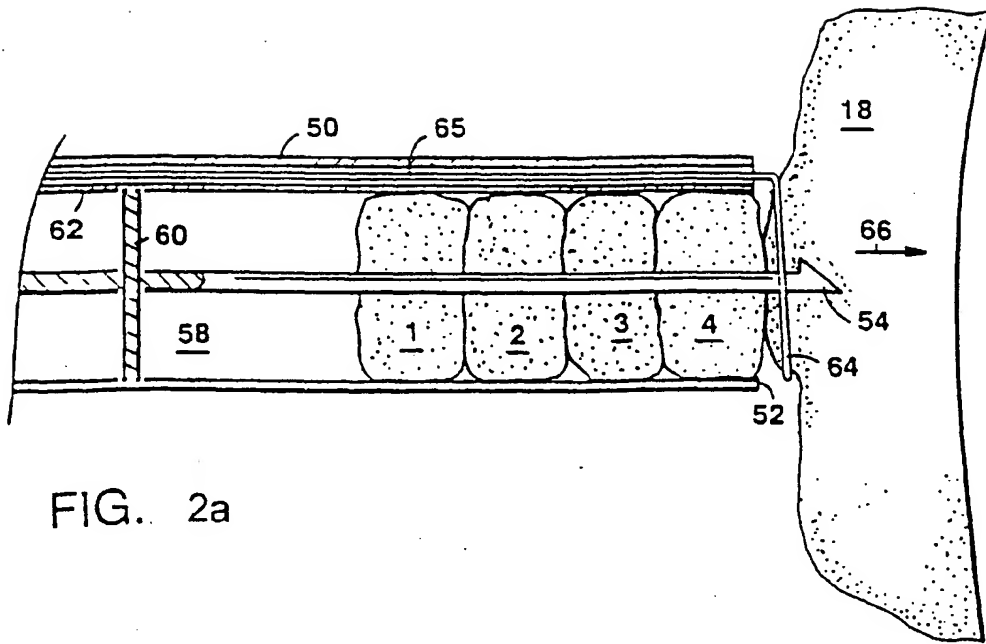


FIG. 2a

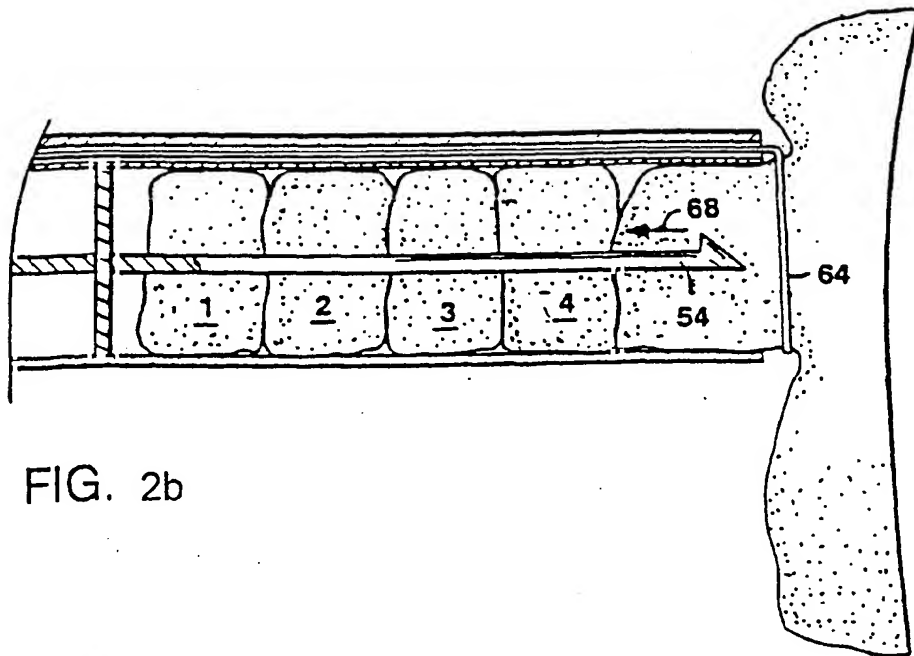
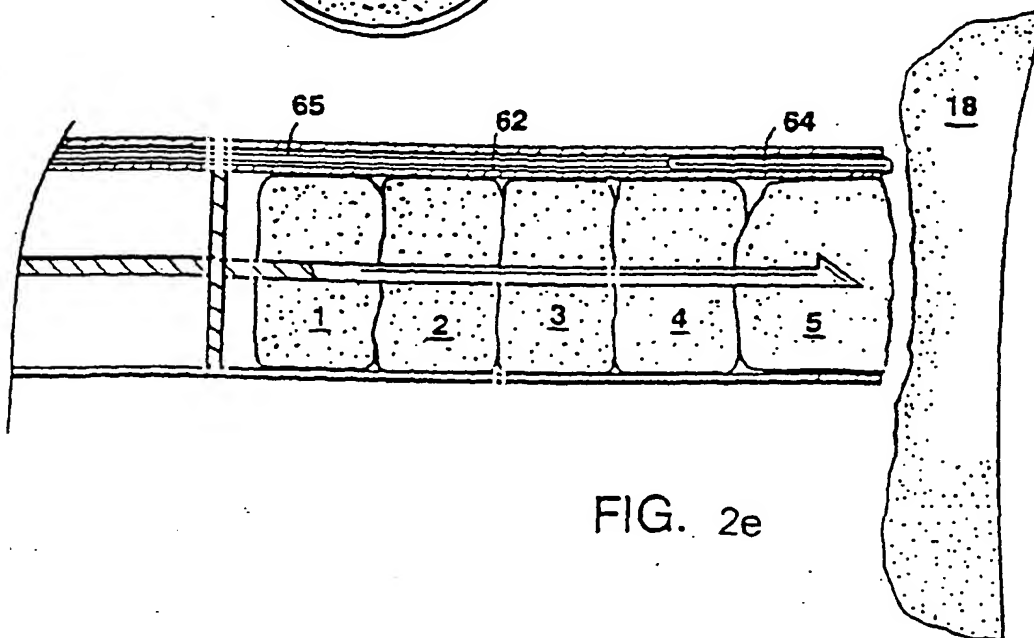
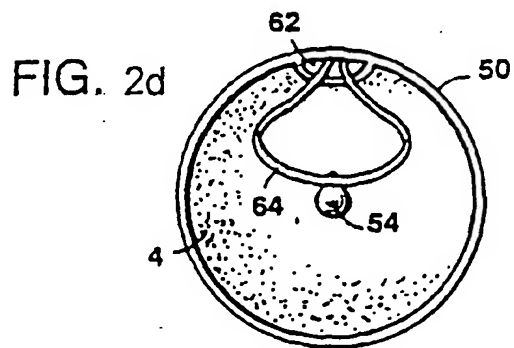
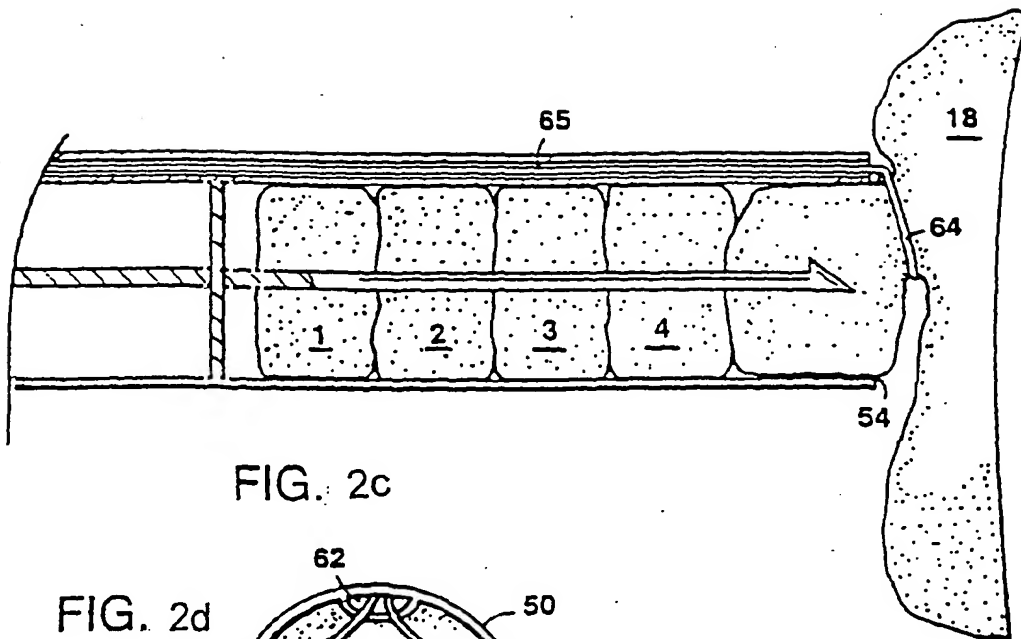
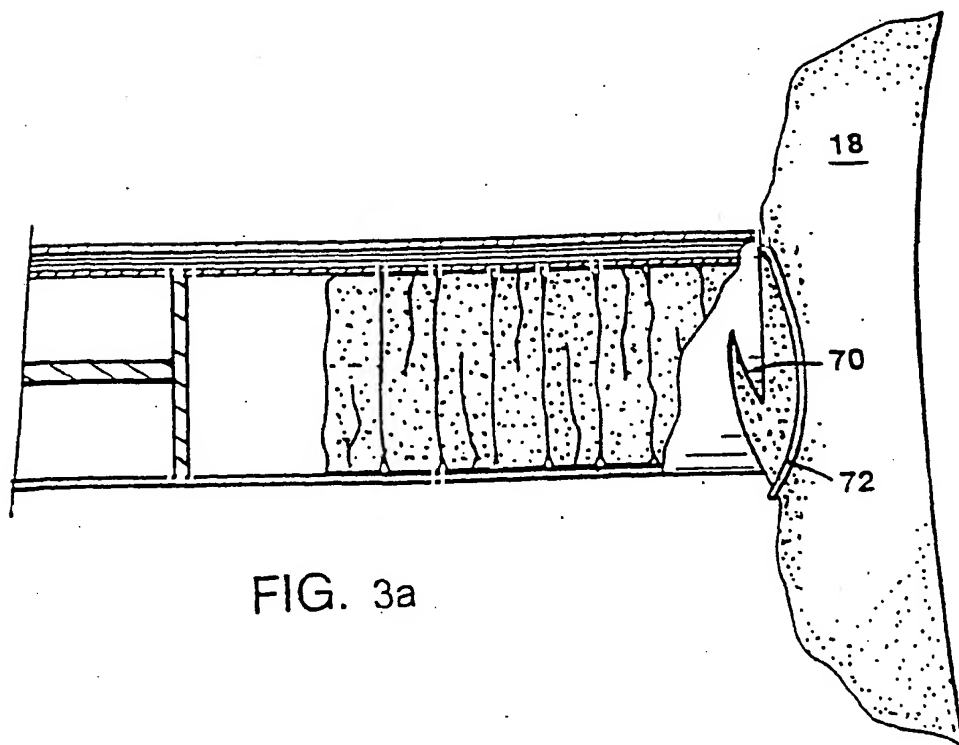
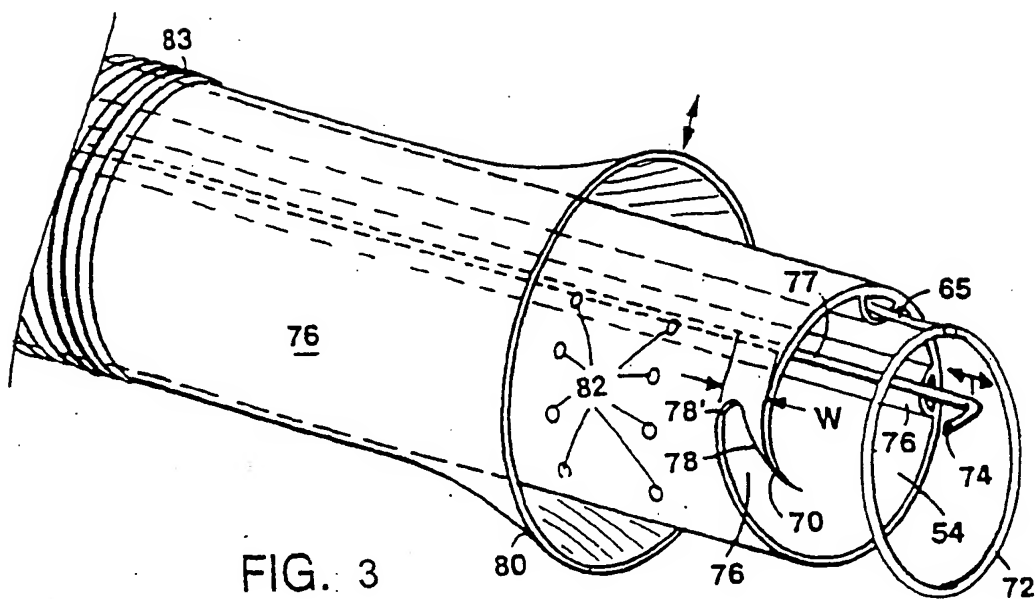


FIG. 2b





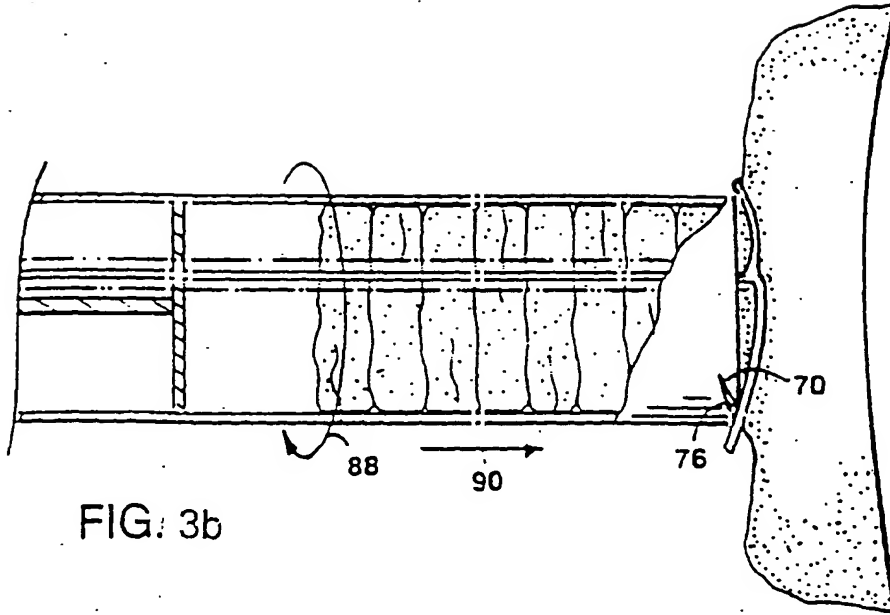


FIG. 3b

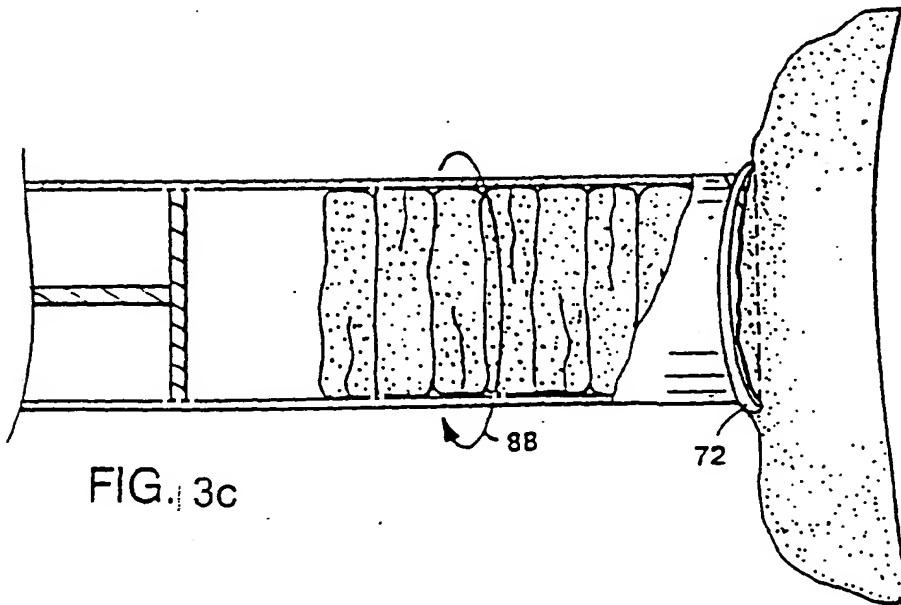


FIG. 3c

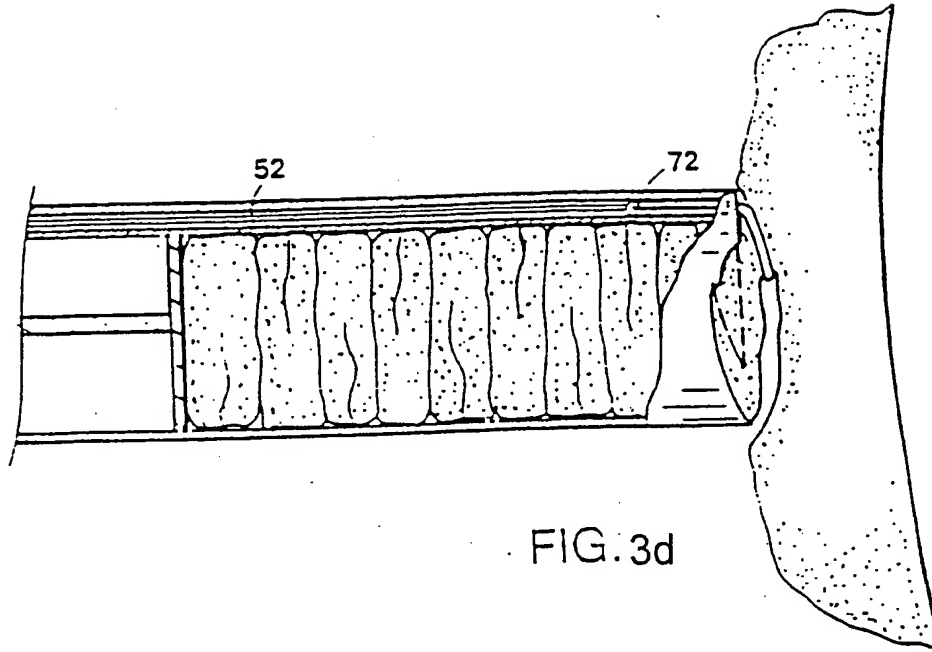


FIG. 3d

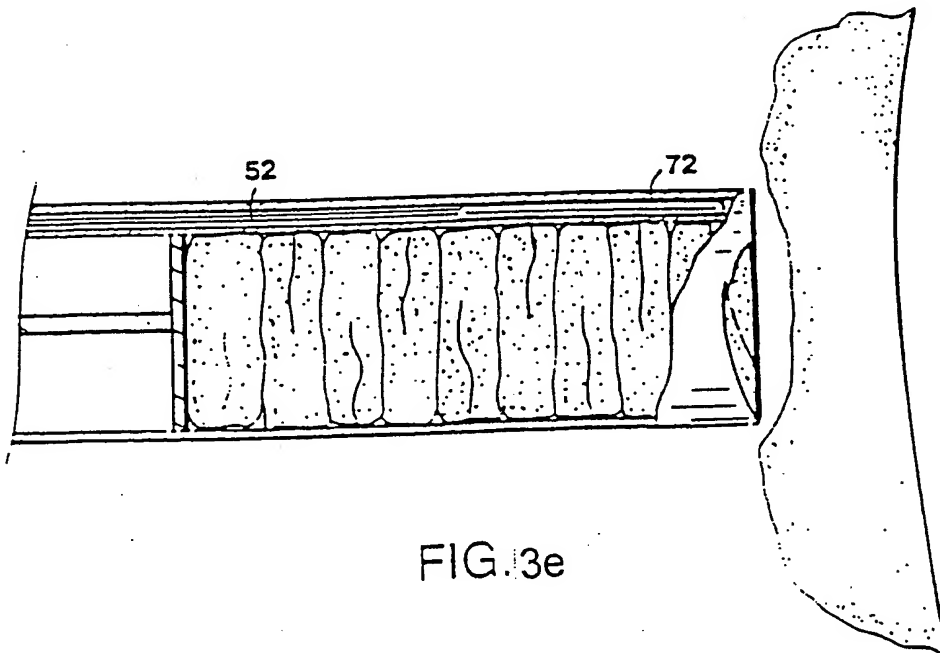
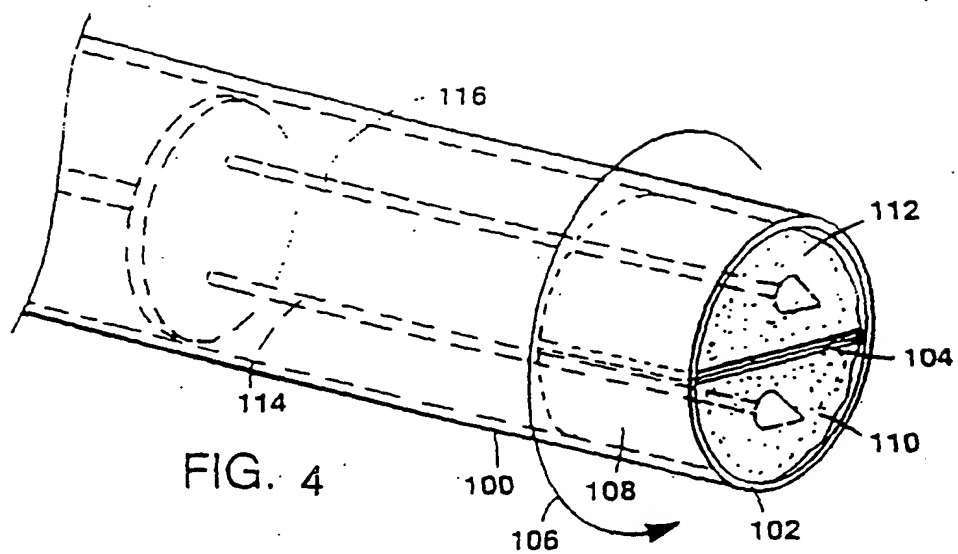
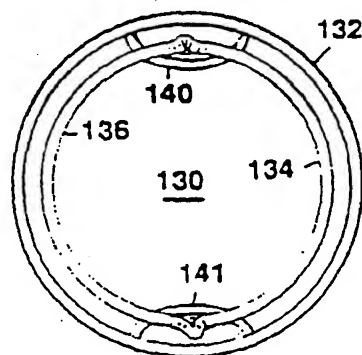
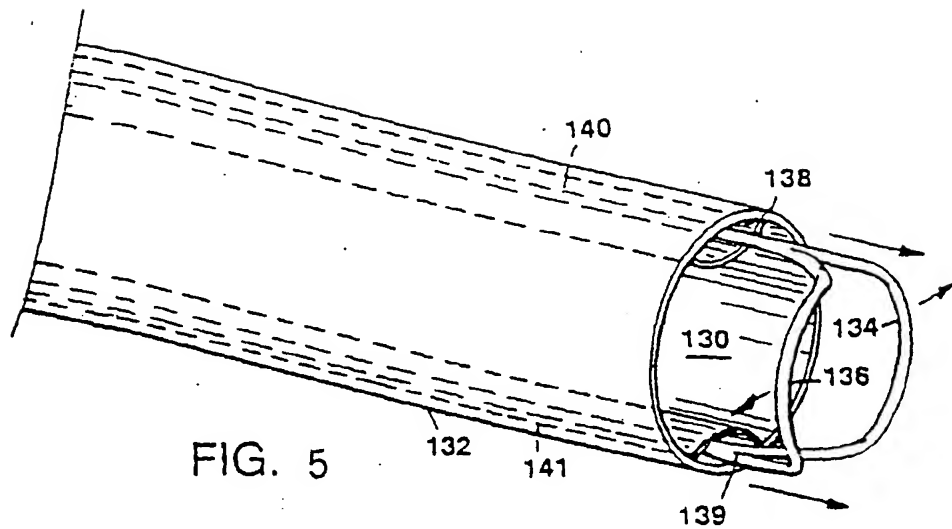


FIG. 3e





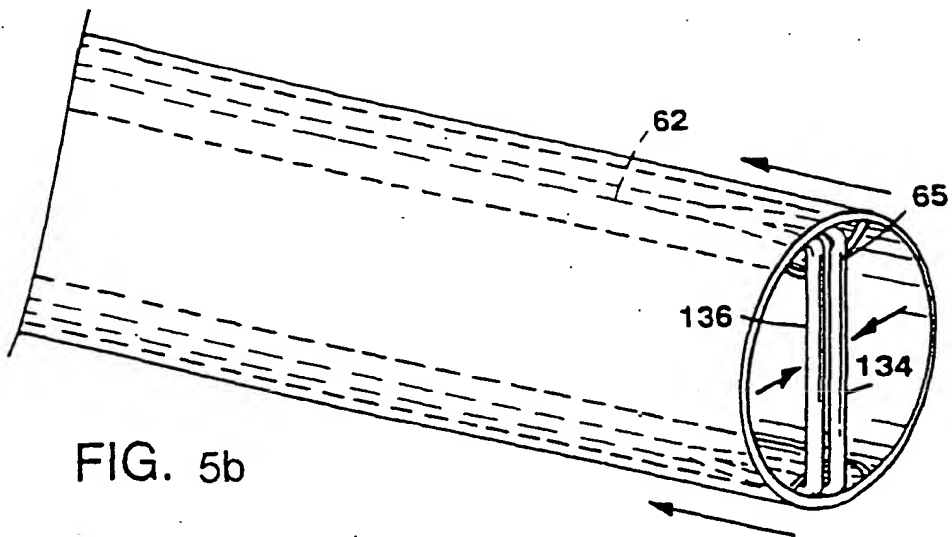


FIG. 5b

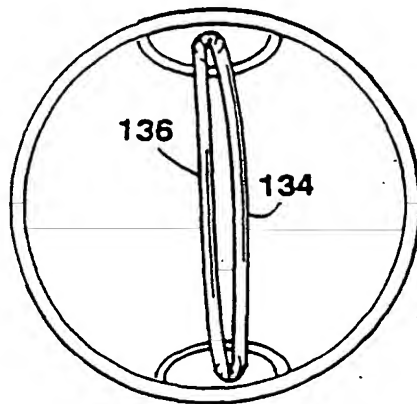


FIG. 5c



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 02 10 2018

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	US 5 197 484 A (KORNBERG ET AL.) 30 March 1993 (1993-03-30)	1-6	A61B10/00
Y	* column 8, line 36 - line 56 * * column 10, line 25 - line 38; figures 12,13 *	7,8	
X	US 5 133 360 A (SPEARS) 28 July 1992 (1992-07-28)	1-6	
Y	* column 8, line 9 - column 9, line 2; figure 7 *	7,8	
A	US 4 461 305 A (CIBLEY) 24 July 1984 (1984-07-24)	7,8	
	FR 2 625 429 A (C.M.P.L.) 7 July 1989 (1989-07-07)	7,8	
	* page 3, line 28 - line 34; figure 1 *		
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61B
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 5 September 2002	Examiner Moers, R
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

EPO FORM 1503 03.82 (P04C01)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 02 10 2018

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

05-09-2002

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5197484	A	30-03-1993	US	5111828 A	12-05-1992
			US	5353804 A	11-10-1994
US 5133360	A	28-07-1992	AU	1642392 A	06-10-1992
			WO	9215250 A1	17-09-1992
US 4461305	A	24-07-1984	NONE		
FR 2625429	A	07-07-1989	FR	2625429 A1	07-07-1989

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

THIS PAGE BLANK (USPTO)

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE BLANK (USPTO)